

REMARKS

Applicant has amended claims 1 - 4, and 7. Applicant has added new dependent claim 8. Claims 1 - 4 and 7 - 8 are currently pending in this application.

Applicant respectfully requests reconsideration of this application in view of the above amendments and the following remarks.

I. SUMMARY OF OFFICE

The Examiner rejected claim 4 under 35 U.S.C. § 112, second paragraph, because, in the Examiner's opinion, the claim failed to particularly point out and distinctly claim the subject matter of the invention.

The Examiner rejected claims 1-4 under 35 U.S.C. §102(e) as being anticipated by Knappe et al. (U.S. Pat. No. 6,537,496).

The Examiner rejected claim 7 under 35 U.S.C. §103(a) as being unpatentable over Knappe et al. (U.S. Pat. No. 6,537,496) in view of Porter et al. (U.S. Pat. No. 5,709,838).

II. TRAVERSAL OF REJECTION IN OFFICE ACTION

A. Response to Claim Rejections under 35 U.S.C. §102(e)

A rejection under §102 requires that each and every element of the claimed invention be taught by the cited reference. Since a patent must describe and enable an invention to one skilled in the art, an anticipatory patent by definition must place the claimed invention into the public domain.

The Examiner states in the outstanding Office Action that Knappe inherently has “elongated pores”. This statement is not supported by the specification of Knappe and the result of “elongated pores” that leaves a useful, functioning test strip in Knappe is certainly not inherent. As expressly stated in Knappe, any bending or flexing causes the test strip to form folds that pull away from the inner layers of the test strip. (See Knappe at column 4, lines 51-67.) If the Knappe test strip is forming folds then it is not being stretched, the pores are not elongated and the resulting test strip is useless.

Pursuant to MPEP §2112.01, the claimed product and the prior art product must be identical in order to presume that the functions of the prior art product are inherent. Knappe does not disclose the flexing or bending of a test strip that prevents the formation of folds. In fact, Applicant recognized this problem at page 15, lines 13-17 of the specification where it expressly states that the many layers of the test strip may separate.

No where does Knappe even consider that a flexed test strip does NOT form folds. Therefore, the claimed product (i.e., a test strip flexed to prevent folds) is NOT identical to the prior art product (i.e., flexed test strips that have folds) as required by the MPEP, and the Examiner cannot rely on the inherency of Knappe as the basis of an obviousness rejection. Knappe clearly does not disclose test strips that do not have folds.

In addition to the improper basis for the §102 rejection, Applicant amended independent claims 1 through 4 so that they expressly call for features that are not disclosed or even suggested in Knappe. In claim 1, Applicant expressly calls for the flexing of a test strip that avoids the formation of folds on the test strip's inner side. In claim 2, the inner side of the test strip is supported at least partially along its inner side to further prevent the separation of the layers of the test strip. (See, *inter alia*, page 15, lines 10-11 and Figure 3.) In claim 3, Applicant has included the step of applying pressure points in order to avoid the compression (and therefore, the folds) normally associated with flexing a test strip.

As stated in Applicant's amended claim 4, the pores are elongated by physically stretching the test strip in the direction of the intended liquid flow. Knappe does not disclose the physical stretching of a test strip, let alone stretching "in the direction of the intended liquid flow." New claim 8 depends from claim 4 and includes the feature of a living hinge to apply controlled pressure on the test strip as supported in the specification at page 15, lines 9-10.

Clearly, Knappe (the '496 patent) does not disclose each and every element of the claimed invention as amended and, therefore, cannot anticipate Applicant's invention.

Knappe discloses an overlay that attaches to a test strip and covers the analyte-sensitive fields of the test strip in order to ensure uniform distribution of a sample over the analyte-sensitive fields.

Although Knappe shows a test strip being flexed, Knappe indicates that the flexing does not have a positive benefit because of the compressing of the “inner” side of the test strip. According to Knappe, since test strips are comprised of multiple layers that are stacked on top of one another (i.e., like a sandwich), the layer on the inner side forms folds that pull away from inner layers of the test strip. (See Knappe at column 4, lines 51 - 67.) As stated previously, Applicant also recognized this problem and stated this problem in the specification.

Knappe does not disclose the positive effects of bending or elongating the micro-pores of a test strip when the folds or separation are prevented! Knappe also does not disclose the use of pressure points as claimed in Applicant’s amended claim 3 and new claim 8. Clearly, Knappe does not disclose “each and every feature” of Applicant’s claimed invention. Therefore, Knappe cannot anticipate Applicant’s amended claims 1 - 4 and 7- 8.

Applicant discloses the multi-layer structure of test strips in his specification. Although Knappe identifies the problem associated with flexing the test strip (which creates the aforementioned folds), Knappe’s solution is to place an overlay on the test strip to improve the distribution of the liquid over the test strip. However, Knappe does not realize the advantages of flexing the test strip AND preventing the folds. For this reason, Knappe cannot make obvious Applicant’s invention as claimed.

B. Response to the Obviousness Rejection under 35 U.S.C. §103

Since claim 7 depends from independent Claim 4, the combination of Knappe and Porter still does not disclose the positive benefits of stretching the micro-pores and preventing the formation of folds. Accordingly, the cited combination cannot make obvious Applicant’s amended claim 7.

III. NON-ART MATTERS

In the Final Office Action, the Examiner rejected claim 4 under 35 U.S.C. §112, second paragraph, because the Examiner believes that claim 4 must disclose how the micro-pores are elongated.

Applicant does not agree that a means must be disclosed in claim 4 and therefore believes that this rejection is improper. Nevertheless, in the interest of moving this application along, Applicant has amended claim 4 by expressly including language in claim 4 that the micro-pores are physically bent. Applicant believes that he has fully addressed the rejection under §112.

Applicant mailed an Information Disclosure Statement on July 28, 2004, which included Form PTO-1449 listing thirteen items (eight U.S. patents and five “other” documents) for the Examiner to consider during the examination of the present application. (However, three of the U.S. patents were already cited by the Examiner in the Form PTO-892 that accompanied the Office Action dated January 20, 2004, and were inadvertently added to Form PTO-1449.) Applicant’s postage pre-paid postcard that accompanied the IDS was date-stamped on July 30, 2004, by the PTO indicating receipt of the IDS before the mailing of the Final Office Action. However, an initialed copy of Form PTO-1449 did not accompany the Final Office Action. Applicant respectfully requests that the Examiner return an initialed copy of Form PTO-1449 as an indication that the Examiner considered the references submitted and to ensure that the references are properly listed on any patent that may issue from the present application.

IV. CONCLUSION

Applicant believes he has addressed all of the issues raised by the Examiner in the Final Office Action. Applicant respectfully submits that the Examiner’s reliance on the “inherent” properties of Knappe is inappropriate because Knappe does not in fact disclose the identical apparatus as disclosed by Applicant (i.e., a flexed test strip without folds). Accordingly, the Examiner must withdraw the obviousness rejections based on Knappe. Moreover, Applicant has amended all of the pending claims so that each claim includes a feature that is not disclosed or suggested in Knappe (or in Knappe in view of Porter). In view of the above amendments and remarks, Applicant respectfully requests reconsideration of the present application and the issuance of a Notice of Allowance for claims 1 - 4 and 7 - 8.

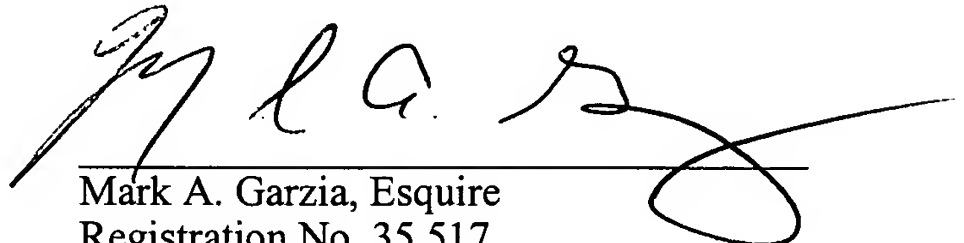
Should the Examiner have any questions regarding this application, he is invited to telephone the undersigned in order to expedite the examination procedure.

Enclosed is a self-addressed, postage pre-paid postcard for the U.S. Patent and Trademark Office to date stamp in order to acknowledge receipt of this communication.

Respectfully submitted,

Kenneth A. Alley

Date: 10 JAN 2005

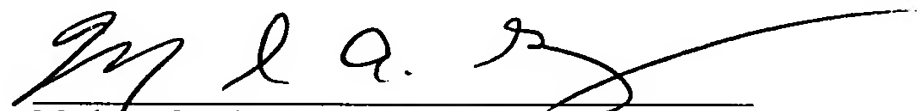

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CERTIFICATE OF MAILING

I hereby certify that this communication, along with any paper or fee indicated as being enclosed, is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

10 JANUARY 2005
Date


Mark A. Garzia